

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization  
International Bureau



(43) International Publication Date  
22 August 2002 (22.08.2002)

PCT

(10) International Publication Number  
WO 02/064196 A1

(51) International Patent Classification<sup>7</sup>: A61M 5/142 // 5/315

(21) International Application Number: PCT/DK02/00098

(22) International Filing Date: 12 February 2002 (12.02.2002)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:  
PA 2001 00240 14 February 2001 (14.02.2001) DK

(71) Applicant: NOVO NORDISK A/S [DK/DK]; Novo Allé, DK-2880 Bagsværd (DK).

(72) Inventors: LARSEN, André; Skovengen 3, DK-2791 Dragør (DK). PEDERSEN, Thomas; Gl. Hellebækvej 1D, DK-3000 Helsingør (DK). ENGGAARD, Christian, Peter; Dyrehavevej 14, DK-3400 Hillerød (DK). BENDSEN, Henrik; Gasværksvej 12A, 5, DK-1656 Copenhagen V (DK). HANSEN, Michael, Ejstrup; Axel Brahesvej 42, DK-5474 Veflinge (DK). MØLLER, Claus, Schmidt; Paludan Müllers Vej 7, DK-3480 Fredensborg (DK). PEDERSEN, Carsten, Bitsch; Holsterbrovej 57D, DK-7600 Struer (DK).

(81) Designated States (national): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZM, ZW.

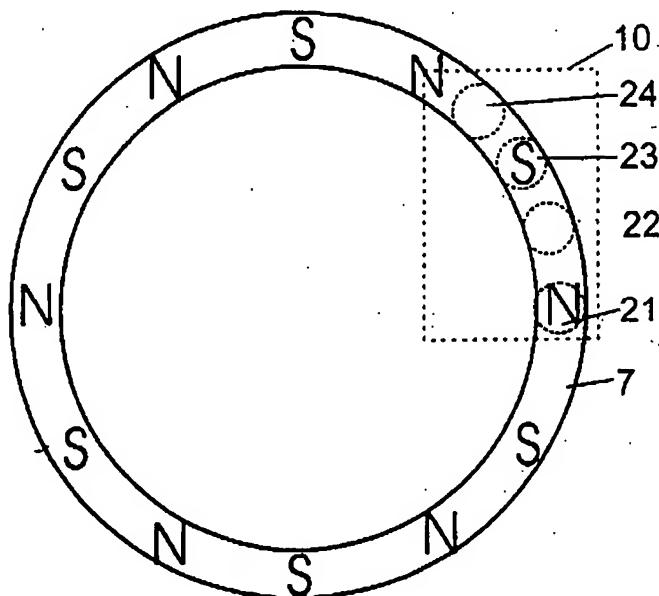
(84) Designated States (regional): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

- with international search report
- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: ELECTRONICALLY CONTROLLED INJECTION OR INFUSION DEVICE



(57) Abstract: A device for injecting preparations is controlled by a sealed circuit block (10) containing integrated sensors (17; 21, 22, 23, 24) which monitors selected parameters. Two pairs of integrated Hall elements (21, 23 and 22, 24) monitors movements relative to a sine formed magnetic field presented along the perimeter of a multipoled magnetised ring (7). The Hall elements in each pair are displaced 180° magnetically relative to each other and the two pairs of Hall elements are displaced 90° magnetically from each other. Each pair is coupled to a differential amplifier (25, 26) to provide a cosine and a sine signal, respectively. The sine signal is divided by the cosine signal to create a tangent signal as an entrance to a table showing the angle of the movement.

WO 02/064196 A1

## ELECTRONICALLY CONTROLLED INJECTION OR INFUSION DEVICE

5 The invention relates to electrically controlled devices for injecting or infusing medical preparations in the human body.

10 For patients suffering from diseases, which provoke the need for frequent administration of liquid medicine which is injected or infused into the patient, administration devices have been developed in the form of syringes by which a dose of medicine can easily be set and successively injected by the patient himself. Also pumps have been developed which pumps continuously or semi continuously, i. e. in repetitive small doses, infuse a small flow of the medicine through a catheter into the body of the patient.

15 To work automatically the pumps have to be equipped with a power supply which can drive the pump. The power supply is mainly an electric battery supplying an electric motor driving a piston into a cartridge to successively press out the content thereof through the catheter. However, pumps may be differently designed as membrane pumps or as another kind of cyclic working pumps, but common to most pumps is, that they are electric powered from an electric battery and controlled by an electric circuit, which is programmed to power the pump 20 in a way ensuring the administration of the correct flow of medicine. The electric circuit can further receive information from sensors distributed in the pump to survey that the pump is working properly and the circuit can control the powering in a way which promotes the correct working.

25 Originally syringes were mechanically working devices on which the patient could set a wanted dose and thereafter inject the dose by manually pressing down an injection button. In the device described in WO 9730742 the dose setting and the injection is still performed manually but control functions are performed electrically through sensors distributed in the device which sensors sends information to a control circuit by which the device is surveyed.

30 As described in WO 9733638 the sensors may be switches which occupy "off" or "on" positions reflecting the positions of mechanical parts of the device. Also pulse generators can be realised as switches, which are alternating closed and opened. Signals are sent from the sensors to an electronic circuit in which the signals are evaluated and corresponding messages are sent to a display on which the condition of the device can be read.

The electronic circuit may be a common commercial circuit or an integrated circuit block which is designed and manufactured specifically to be used in the device in question. Once such an integrated circuit block has left the production line as a functioning circuit it is very reliable, and failing of the device is mainly due to the wiring and connections to sensors outside the circuit. Especially sensors based on mechanical contacts are rather sensible to wear, dust and oxidation.

Consequently it is an objective of the invention to provide an electronic controlled device by which a dose of medicine can be set and injected and in which device wiring and connections outside a sealed integrated electric circuit are reduced to a minimum, e. g. to terminals for connection to a power source and an output to a display which commonly will be large relative to the circuit.

This is obtained by an electrically controlled device for injecting or infusing medical preparations into the human body in which devices the controlling is performed by a sealed electric circuit block receiving signals from sensors which monitors selected parameters describing conditions of the device, which device is characterised in that the sensors are integrated in the sealed circuit block and are of a kind with no mechanically opened or closed switches.

The sensors can be light sensors, e. g. photocells, magnetic sensors, e. g. Hall elements, or coils in which a current is induced by an outer magnetic field, load cells which gives of an electric signal when they sense a mechanical pressure. Common to all these sensors are that their electric conditions are changed without involving any wear and dirt sensible switches. Even emission of light can be obtained by the sealed electronic circuit block by establishing of so-called laser wells.

The sealed circuit block, a power supply for this circuit block, and other electronic components connected to said circuit block may be accommodated in one rigid part of the device. Thereby movable electric connections are avoided.

The rigid part of the device may appropriately be a button which can be used for setting or injecting a dose of a medicine.

At least one of the sensors may be a Hall element.

Such a Hall element may be signalled by a movable magnet fixed to a part of the device to monitor the position of this part relative to the part accommodating the electronic circuit block.

- 5 The sealed electronic circuit block may comprise a timer which may have a first input for a reset signal, a second input for a signal activating a read out of the timer, and an output to a display displaying the read out of the time lapsed after the latest receipt of a signal on said first input, the injection device further being provided with a sensor connected to the first input of said timer, which sensor gives off a signal when the injection button is pressed to move the piston rod, and with a means for optional sending of a signal to the second input to activate the read out of the electronic circuit.
- 10

The electronic circuit in the sealed circuit block may be so designed that a signal sent to said second input opens the energising of the Hall element and other energy consuming sensors.

- 15 This way the Hall element and other sensors may be energised only when they are going to perform a monitoring function whereas they are switched off when the device is stored. During storage power is still supplied to the timer and memory functions.

- 20 The circuit may further be so designed that a signal is sent to said first input when a Hall element in the sealed electronic circuit block detects a change of the position of a magnet relative to the part accommodating the sealed electronic circuit block.

- 25 The means optionally sending a signal to the second input may be a switch outside the sealed electronic circuit block. This switch may be a conventional switch in the power supply for the Hall element.

When the device is so designed that the Hall element is not activated during the setting of a dose but is activated during the injection it can count the number of units injected and may at the same time send a signal to said first input.

- 30 The magnet may have the shape of a ring having a number of alternating poles along its perimeter

- 35 To measure the size of an injected dose it is necessary to measure the extent of the rotation of the magnet ring relative to the button accommodating the sealed circuit block. This is ob-

tained by using a number of Hall elements positioned along an arc of a circle which follows a section of said magnet ring. At the start of the rotation the relative position of the magnet ring relative to Hall elements is defined by the magnetic field which is detected by the Hall elements.

- 5 On the basis of the field measured a relative angle, the start angle, is calculated. By rotation the field measured varies with the rotation angle and at the end of the rotation the relative angle, the end angle, is calculated. These angles can be found in a table over corresponding detected magnetic fields and angular positions. Such a table can be included in the sealed circuit block. Further it is detected how many times poles having the same polarity are
- 10 passed and each time this happens the angle between two poles with the same polarity is added to the rotation angle, which is calculated as the end angle minus the start angle. Knowing the number of units which are injected by a 360° rotation the rotation angle can easily be converted to injected units.
- 15 In an embodiment of the device according to the invention 4 Hall elements may be used and the magnet ring may have 12 poles. The Hall elements may be so distributed along an arc of a circle that, a first Hall element is positioned facing a north pole a third Hall element is facing a neighbour south pole, a second Hall element is facing the neutral zone between said north pole and said south pole, and a fourth Hall element is facing the neutral zone between said 20 south pole and the succeeding north pole, i. e. the length of the circular arc is 45°.

- 25 The magnet poles of the magnet ring creates a sine shaped magnet field with a full sine wave for each pair of poles. With 12 poles on the magnet ring a phase angle of 360° for the sine curve corresponds to 60° of rotation. With the Hall elements placed as described the phase angle at the respective positions of the Hall elements are 0°, 90°, 180°, and 270°, respectively.

- 30 The outputs from the first and the third Hall element may be connected to input terminals on a first differential operational amplifier and the outputs from the second and the fourth Hall elements are connected to input terminals on a second differential operational amplifier, and output signals from the differential operational amplifiers are through analogue/digital converters and a normalising circuit lead to a look up table circuit wherein one signal is divided with the other to obtain a tangent function which is used as entrance to a table.

By coupling the Hall elements which are magnetically 180° displaced relative to each other to a differential amplifier immunity against external magnetic fields is obtained. By the 90° displacement between a first set of Hall elements, comprising the first and the third Hall element, and the second set of Hall elements, comprising the second and the fourth Hall element a quadrature measurement is obtained by which one signal is a sine signal and another is a cosine signal. By division of these signals an tangent function is obtained. As tangent value is independent of the amplitudes of the sine and the cosine signals the sensor will be insensitive to variations in the magnetic field strength and consequently independent of the air gap between the magnet ring and the sensor. The tangent value obtained refers to a magnetic angle which can be found in the table. Also account must be taken for the number of times a 360° magnetic cycle has been run through. On the basis hereof the rotation angle for the dose setting drum can be found when the number of poles on the ring is known.

In the following the invention is described in further details with references to the drawing, 15 wherein

Figure 1 shows a detail of an injection device with an integrated circuit block according to the invention

20 Figure 2 shows schematically the relative positioning of a magnet ring and a sealed circuit block containing four Hall elements.

Figure 3 shows a block diagram of the integrated circuit transforming the readings of the Hall elements into a rotation angle of the dosing mechanism.

25 Figure 1 shows the proximal end of an injection device comprising a combined dose setting and injection button 1, which button is rotated to set a dose and pressed in an axial direction to inject the set dose. The button 1 is fixed to a tubular element 2 so that element 2 will follow as well rotational as axial movements of the button 1.

30 When the button 1 is rotated to set a dose the tubular element 2 is rotated too. The tubular element 2 has a flange 3 carrying a number of  $\wedge$ -shaped teeth 4 which engages corresponding depressions in an internal circumferential flange 5 in a dose setting drum 6 concentric with the tubular element 2 so that said drum 6 is rotated with said tubular element 2 and the button 1 when said button is rotated to set a dose. When the dose setting drum 6 is

rotated it will, due to a not shown thread connection between said drum 6 and a not shown housing concentrically surrounding said dose setting drum 6 and said tubular element 2, be screwed outward in said housing and will lift the button 1 up from the end of said housing.

5 The button 1 accommodates an electronic unit mounted on a circuit board 15 and comprising a sealed circuit block 10, which is powered by a battery 11 through contacts 12 and 13. From the circuit block 10 output signals are fed through a multi wire cable to a LCD display 14. Further the sealed circuit block 10 has an integrated magnetic sensible component 17 which can give off a signal when it is moved relative to a magnet ring 7 at the upper 10 end of the dose setting drum 6. The magnetic ring 7 is magnetised to have a number of alternating magnetic poles along its perimeter. When the dose-setting drum rotates relative to the button 1 the sensor 17 will give off a signal reflecting the magnetic field sensed by this sensor. The end wall of the button 1 is provided with a window 8 made from a transparent material to allow inspection of the display 14.

15 The electronic circuit in the sealed circuit block 10 comprises a timer which is started when a dose is injected and the status of which is shown for a while in the display 14 when the button 1 is pressed by pressing the window 8 so that the electronic unit in the button 1 is moved against the force of a spring 19 whereby a button 20 of a switch 18 is pressed to activate said switch.

When the switch 18 is activated it may give off a signal inducing a read out of the stopwatch. When the sensor 17 is a Hall element the switch 18 can be a main switch opening for the energising of this Hall element.

25 Injection is detected by the sensor 17 when the ring 7 with alternating magnetic poles is rotated relative to the button 1. During the setting of a dose such relative rotation is not performed. At the beginning of its movement the button is moved axially relative to the dose setting drum 6 until the teeth 4 on the flange 3 of the tubular element 2 are moved out 30 of engagement with the depressions in the flange 5 of the dose setting drum 6.

When the button 1 is pressed the activation of the switch 18 will provide a signal which directly or indirectly triggers the circuit block 10 to activate the display 14 for a while to show the status of the timer. As a test all segments are shortly turned on to show that they 35 are all operative before information is shown.

If a dose has been set, further pressing of the button 1 will bring the teeth 4 out of engagement with the depressions in the flange 5 on the dose setting drum 6 whereby said dose setting drum is allowed to rotate relative to the button 1 which relative rotation is detected by the sensor 17 which generates a signal in the integrated circuit block 10 indicating that an injection is made. When the button 1 is released after an injection all the segments are shortly turned on one by one.

The described embodiment allows integration of all electronic components in the button 1 so that only the magnet ring 7 must be provided in the device outside the button. In other embodiments wherein no parts rotate during injection, injection may be detected by using a sensor sensing the movement of a piston rod, which is magnetised with alternating poles. In still other embodiments wherein the button always follows the rotation of the dose setting drum the rotation to be detected may be the relative rotation between the button and a finger pad at the end of the button, which finger pad follows the button during the dose setting but relative to which the button is rotated during injection. The circuit may be so programmed that such relative movement is only taken as an indication of an injection when the button is pressed.

Although only magnetic acting signal generators are mentioned the use of other, e.g. optical signal generators and sensors lies within the scope of the invention. Also the button in which the electric components are integrated, although it is described as a fixed part of the device, may be removable so that it can be moved from a possible disposable injection device and mounted on a new one, only the devices must be provided with the necessary signaller to generate signals from the sensors. This may appropriately be obtained by moulding such signallers into the syringes by using a mouldable magnetic plastic material.

Figure 2 schematically shows the magnet ring 7 seen from the end of the device and shows the positions of a first 21, a second 22, a third 23, and a fourth 24 Hall element in the sealed circuit block 10 relative to the poles of the magnet ring 7. This position can be seen as a start position from which the button is screwed away during the setting of a dose and to which the button returns when a set dose has been injected. In the shown embodiment the ring 7 is magnetised to present along its perimeter a sinus shaped magnetic field oscillating 360° between two poles having the same polarity. With twelve poles along the perimeter of the ring a 360° magnetic angle will correspond to a 60° rotation of the button 1.

When energised during the injection of a set dose the Hall elements 21-24 works together with the magnet ring 7 to monitor the relative rotation of the button 1 relative to the drum 6 as the length of this rotation is proportional with the number of doses injected. In the embodiment shown in figure 2 this monitoring is made by leading the output signal from the first 5 21 and the third 23 Hall elements to the inputs of a differential operational amplifier 25 as shown in figure 3. The output signal from the operational amplifier 24, which is an analogue signal proportional with the cosines of the phase angle of the rotation relative to the start position, is digitised by an AD converter 27. It shall be noticed that this phase angle is calculated relative to the magnet poles so that a rotation which brings a Hall element from a pole 10 with one polarity to the next pole with the same polarity is defined as a phase angle of 360° which in the shown example corresponds to a 60° rotation of the drum 6.

Similarly the second 22 and the fourth 24 Hall element is coupled to the inputs of a differential operational amplifier 26 from which the output signal which is proportional with the sinus 15 of phase angle is sent through an analogue/digital converter 28. The signals from the AD converters 27 and 28 are normalised in a circuit 29 which has two output terminals 30 and 31 which gives off signals which can address a look up table in a circuit 32 to provide at an output 33 an output signal indicating the rotation angle of the drum 6 relative to the button 1. When the number of units to be injected per 360° rotation of the drum 6 is decided the output 20 from the table can be used for calculating the number of units which have been injected.

The operational amplifiers 25 and 26, the A/D converters 27 and 28, the normalising circuit and the look up table can all be integrated in the sealed circuit block. The output signal from the table 32 can also internally in the circuit block 10 be stored in a storage from which a 25 likewise integrated driver for the display 14 is driven to make the display shown the latest injected dose.

Other distributions and numbers of magnetic poles, other numbers and constellations of sensors, and other handling and calculating circuits can be used without deviating from the scope of the invention. 30

## Claims

1. An electrically controlled device for injecting or infusing medical preparations in the human body in which device the controlling is performed by a sealed electric circuit receiving signals from sensors which monitors selected parameters describing conditions of the device, characterised in that the sensors are integrated in a sealed circuit block and are of a kind with no mechanically opened or closed switches.  
5
2. An electrically controlled device according to claim 1, characterised in that the sealed circuit block, a power supply for this circuit block and other electric components connected to said sealed circuit block are accommodated in one rigid part of the device.  
10
3. An electrically controlled device according to claim 2 characterised in that said rigid part of the device is a dose setting and injection button.  
15
4. A device according to claim 1, 2 or 3, characterised in that at least one sensor is a Hall element.  
20
5. A device according to claim 4, characterised in that the Hall element is signalled by a movable magnet fixed to a part of the device to monitor the position of this part relative to the part accommodating the sealed electric circuit block.  
25
6. A device according to claim 4 or 5, characterised in that the sealed electronic circuit block comprises a timer and has a first input for a reset signal, a second input for a signal activating a read out of the electronic circuit, and an output to a display displaying the read out of the time lapsed after the latest receipt of a signal on said first input, the sealed circuit further being provided with a sensor connected to said first input, which sensor gives off a signal when the injection button is pressed to move the piston rod, and with a means for optional sending of a signal to the second input to activate the read out of the electronic circuit.  
30
- 7 A device according to claim 6, characterised in that the sealed electronic circuit is so designed that a signal sent to the second input opens the energizing of the Hall element and other energy consuming sensors.

8. A device according to claim 6 or 7, characterised in that the Hall element is designed to send a signal to the first input when it detects a change of the position of the magnet relative to the part accommodating the sealed electric circuit .
- 5 9. A device according to claim 6, 7 or 8, characterised in that the means optionally sending the second signal is a switch outside the sealed circuit block .
10. A device according to anyone of the previous claims 5 – 9, characterised in that the magnet has the shape of a magnet ring presenting a sinus shaped magnetic field along the perimeter.
11. A device according to claim 10 characterised in that a number of Hall elements is provided , which Hall elements are positioned along a circle arc which follows a section of said magnet ring.
- 15 12 A device according to claim 11 characterised in that four Hall elements are provided
- 13 A device according to claim 12 characterised in that the said arc of a circle corresponds to 1,5 times the arc between two poles and that a first and a fourth Hall element are positioned at opposite ends of the arc and a second and a third Hall element are positioned between the ends of the arc so that the four Hall elements are placed with equidistant spaces along said arc of a circle.
- 20 25 14. A device according to anyone of the claims 10 – 13 characterised in that the number of poles is 12 and the length of the circular arc is 45°.
- 30 15. A device according to claim 13 and 14 characterised in that outputs from the first and the third Hall element are connected to input terminals on a first differential operational amplifier and the outputs from the second and the fourth Hall elements are connected to input terminals on a second differential operational amplifier, and output signals from the differential operational amplifiers are through analogue/digital converters and a normalising circuit lead to a look up table circuit wherein one signal is divided with the other to obtain a tangent function which is used as entrance to a table.

1/2

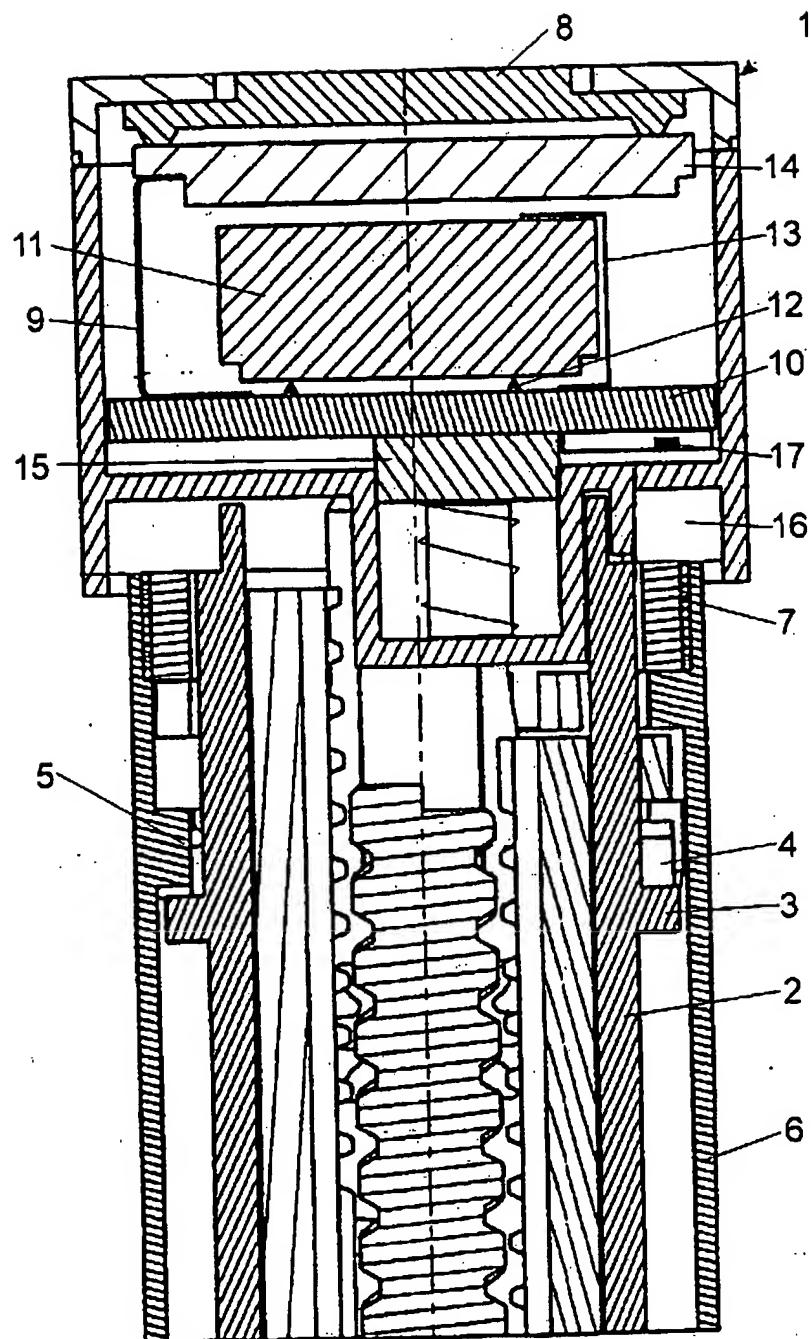


Fig. 1

2/2

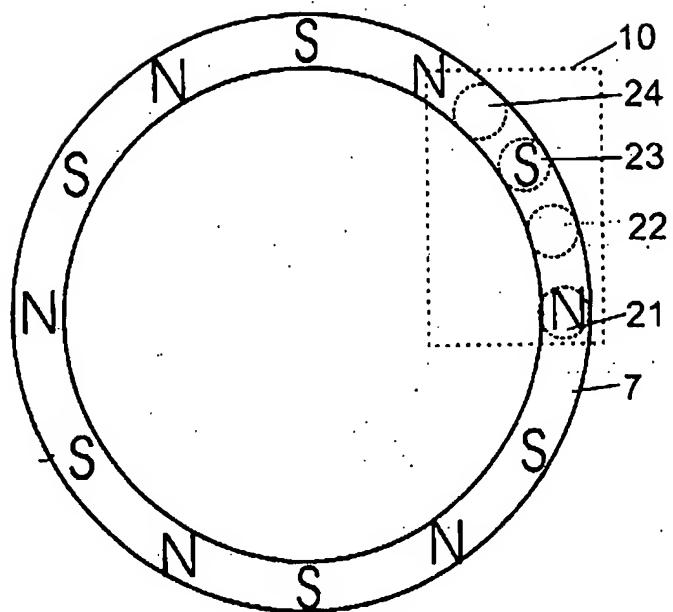


Fig. 2

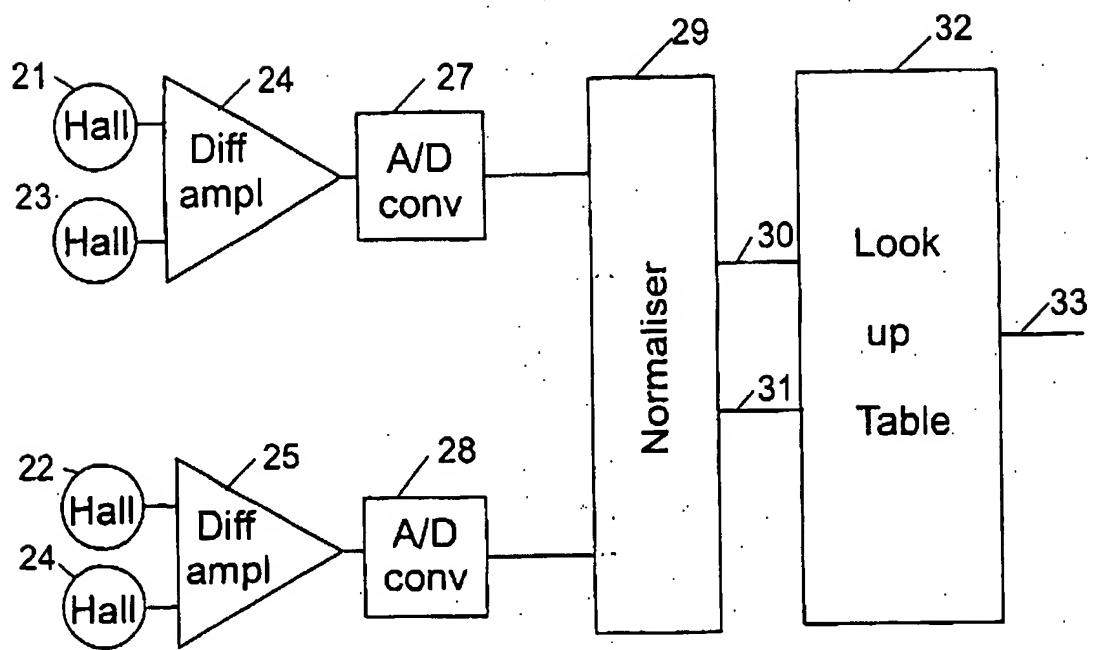


Fig. 3

## INTERNATIONAL SEARCH REPORT

International Application No

PCT/DK 02/00098

A. CLASSIFICATION OF SUBJECT MATTER  
IPC 7 A61M5/142 //A61M5/315

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)  
IPC 7 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

PAJ, INSPEC, EPO-Internal

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P,X	EP 1 095 668 A (BECTON DICKINSON CO) 2 May 2001 (2001-05-02) column 5, line 47 -column 6, line 4	1,2,4-9
P,A	---	3,10-15
A	US 5 728 074 A (CASTELLANO THOMAS P ET AL) 17 March 1998 (1998-03-17) column 12, line 36 - line 57	1-15
A	US 4 515 584 A (ABE HIROSHI ET AL) 7 May 1985 (1985-05-07) column 7, line 28 - line 42	1-15

 Further documents are listed in the continuation of box C. Patent family members are listed in annex.

## \* Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the International filing date
- "U" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the International filing date but later than the priority date claimed

"T" later document published after the International filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"a" document member of the same patent family

Date of the actual completion of the international search

16 May 2002

Date of mailing of the international search report

12.07.2002

## Name and mailing address of the ISA

European Patent Office, P.B. 6818 Patentstaan 2  
NL - 2280 HV Rijswijk  
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl  
Fax: (+31-70) 340-3016

## Authorized officer

Frida Plym Forshell

**INTERNATIONAL SEARCH REPORT**

Information on patent family members

International Application No

PCT/DK 02/00098

Patent document cited in search report		Publication date		Patent family member(s)		Publication date
EP 1095668	A	02-05-2001	EP JP	1095668 A1 2001170176 A		02-05-2001 26-06-2001
US 5728074	A	17-03-1998	US AU EP EP JP WO US US	5536249 A 1939395 A 0749332 A1 0777123 A2 10504729 T 9524233 A1 5593390 A 5925021 A		16-07-1996 25-09-1995 27-12-1996 04-06-1997 12-05-1998 14-09-1995 14-01-1997 20-07-1999
US 4515584	A	07-05-1985	JP JP JP JP DE EP EP US	1648691 C 3009750 B 59008968 A 59008969 A 3378304 D1 0099508 A2 0098592 A2 4636144 A		13-03-1992 12-02-1991 18-01-1984 18-01-1984 01-12-1988 01-02-1984 18-01-1984 13-01-1987